DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

34684d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MAY 4 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Ms. Kimberly Peterson
President
Light Force Therapy, Inc.
650 East Walnut Street
P.O. Box 306
Elizabeth, Colorado 80107

Dear Ms. Peterson:

We are writing to you because your firm is marketing infrared lamp devices known as the "LFT 9000," "Dio LFT 3000," and "Super Nova" for new intended uses that were not cleared or approved by the Food and Drug Administration (FDA). In addition, we believe that certain of your current labeling materials contain false or misleading statements or information.

Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), these products are medical devices because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. The law requires that manufacturers of medical devices obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly-introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

A review of FDA databases disclosed that your firm obtained premarket notification (510(k)) clearances for the "Super Nova," "Acubeam," "Acubeam LFT 5000," and "Dio LFT 3000" devices (K001179 and K022888). It is our understanding that your firm no longer sells the Acubeam or Acubeam LFT 5000. The LFT 9000 appears to be an updated model of the Acubeam LFT 5000 that does not require a separate premarket submission prior to commercial distribution for the same indications for which FDA cleared the Acubeam LFT 5000.

FDA cleared the Super Nova and Acubeam (K001179) for the following intended uses:

> "The Super Nova and Acubeam are indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue

temperature for the temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue."

FDA cleared the Acubeam LFT 5000, Dio LFT 3000, and Super Nova (for one additional indication) (K022888) for the following intended uses:

"The Light-Force Therapy line of infrared lamps are indicated for use to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied."

All claims in your labeling and promotional materials must be limited to the cleared indications listed above. However, our review of the following materials revealed that your labeling and promotional materials go beyond these cleared indications:

1. Your firm's Internet website, http://www.lightforcetherapy.com, from which your products are sold.

2. An informational video entitled "LFT 9000 Show #4," which your firm sends to prospective customers, and which appears as (or is very similar to) a television infomercial through which your firm sells the LFT 9000. The informational video references your website, which offers all the devices for sale.

3. An instructional video entitled "Instructional Video" (Version A) which accompanies the LFT 9000 device sold to customers.

4. An information packet regarding your devices in a folder entitled "LIGHT FORCE THERAPY," which your firm sends to prospective customers. The information packet contains pricing and other information about how to purchase your devices.

5. A newsletter called "LFT Spring Newsletter -- Spring 2004," which current or prospective customers can sign up to receive through your website.

These items make statements about intended uses for the LFT 9000, Dio LFT 3000, and/or the Super Nova for which you do not have FDA clearance or approval. Examples of such statements include, but are not limited to, the following:

- "[I]t can be used on about any type of pain."
- "[I]t even helps relieve stubborn chronic pain."

- "[W]onderful for conditions like . . . tennis elbow, nerve pain, [and] tension headaches. . ."
- "[H]elps relieve pain from . . . tendonitis [and] bursitis. . ."
- "Light Force Therapy a remarkable therapeutic light"
- "Light therapy."
- "[I]t is cleared by the FDA to relieve general pain."
- "Light Force Therapy's products were cleared by the FDA to relieve pain: safely and effectively."
- "Light Force Therapy utilizes the technology of light emitting diodes (LEDs) to produce photons of different wavelengths."
- "Light Force Therapy devices emit energy in the near-infrared spectrum to provide relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue."
- "[F]or pain sufferers to find fast, effective and safe pain relief for a variety of ailments."

These indications constitute major changes or modifications in the cleared intended uses of your products, and therefore require a new premarket submission prior to marketing your devices for these new indications. 21 CFR 807.81(a)(3)(ii). Guidance regarding the kind of information you need to submit to FDA in order to obtain clearance or approval for the additional indications is available through the Internet at http://www.fda.gov/cdrh/devadvice/3122.html.

Your promotion and introduction into interstate commerce of the LFT 9000, Dio LFT 3000, and Super Nova for uncleared indications violates the law. Specifically, these products are adulterated under section 501(f)(1)(B) of the Act because you do not have an approved Premarket Approval Application (PMA) to demonstrate that these products are safe and effective for the new uses for which you are marketing them. In addition, the devices are misbranded under section 502(o) of the Act because you have not submitted a section 510(k) premarket notification to the agency of your intent to introduce the devices into commercial distribution for these new uses. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b).

During several previous communications with your firm and its representatives, FDA advised you that certain intended uses for which you are now promoting your devices could not be included under your 510(k) clearances. For instance, prior to clearance of 510(k) number K001179, FDA required you to modify indications for "pain" to "minor muscle and joint" pain. With regard to 510(k) number K022888, your firm's representative (Mr. Lewis Ward of L.W. Ward and Associates) agreed in a November 14, 2002 facsimile to several changes urged by FDA, including the addition of the word "minor" to the indication for joint and muscle pain, and to the removal of your proposed "chronic pain" indication.

Furthermore, the labeling materials listed above as items 1-4 appear to contain false or misleading statements or information, which include but are not limited to the following examples:

- False statements on your Internet website and in your information packet that the devices are cleared by the FDA to relieve "general pain," that the devices do so "safely and effectively," and that you "design and manufacture products that meet the Food and Drug Administration requirements for pain relief."

- False statement in your informational video that the FDA has "reviewed all of our materials and . . . determined that the claims that we make are in fact accurate." FDA did not review your current materials during the 510(k) process, nor has FDA determined that the claims you make in these materials are accurate.

- Misleading representation of a document on FDA letterhead as being a letter issued to your company granting clearance to your devices and confirming the accuracy of your claims. A review of our records revealed that the letter shown in the informational and instructional videos does not describe any approval or clearance of your products. Moreover, as stated above, FDA did not review your current materials during the 510(k) process, nor has FDA made any statement as to their accuracy. The letter in your videos is actually the text from a 510(k) summary for the "MedX1000" device from a different company, which lists the LFT 9000 as a predicate device.

Your website, the information packet (e.g., a four-page brochure), the informational video, and the instructional video constitute labeling as defined under section 201(m) of the Act, and the false and misleading statements therein render your devices misbranded under section 502(a) of the Act. The false and misleading statements specified above, and any similar statements, as well as the letter incorrectly identified as an FDA endorsement of your products, must be removed from the website, the four-page brochure, the videos, your infomercial, and any similar materials you provide to customers or prospective customers.

You should know that these are serious violations of the law that may result in FDA taking regulatory action against you or your product without further notice if you do not act promptly. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your products, or assessing civil money penalties. Also, federal agencies are informed about Warning Letters such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on these matters now. Please let this office know what steps you have taken to correct these problems within fifteen (15)

working days from the date you receive this letter. We also ask that you explain how you plan to prevent these problems from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to:

Christy Foreman, Acting Chief
Orthopedic, Physical Medicine and Anesthesiology Devices
Division of Enforcement B, Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road, HFZ-343
Rockville, MD 20850

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance or approval and subsequent promotion of your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing and other requirements affect your particular devices, or about the content of this letter, please feel free to contact William Defibaugh at (301) 594-4660, extension 121.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health